DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 27, 2004

The Honorable Rod R. Blagojevich
Governor
State of Illinois
100 West Randolph, Suite 16-100
Chicago, Illinois 60601

Dear Governor Blagojevich:

Thank you for your letter on October 25, 2004, informing me of your efforts to identify foreign versions of influenza vaccine that may be helpful in addressing the unexpected shortage of flu vaccine. You requested the Food and Drug Administration's assistance in making available foreign-version influenza vaccines in a manner that complies with Federal law and I want to work with you on your request.

The Administration is committed to identifying all possible sources of safe and effective influenza vaccine for this year's flu season. In fact, we are having success working directly with manufacturers in other countries and are hopeful that we will have good news soon regarding the availability of more doses of vaccine for this flu season. And we certainly welcome any additional opportunities your state may provide to possibly secure more vaccine in a safe and viable manner. Every safe and effective dose of vaccine helps.

The top priority of the Department of Health and Human Services and FDA is to investigate all viable options to secure additional dosages that are safe for Americans to use. As you must know, we have already identified significant additional supplies from the remaining manufacturer of the U.S. licensed vaccines, increasing the available supply to 61 million doses. Millions of additional doses of the licensed vaccine are being made available for shipment and delivery throughout the Nation in the coming weeks, including to Illinois. We also contacted manufacturers worldwide in an effort to identify increased supplies of safe and effective antiviral drugs that already have been approved for use to treat Americans who either have been exposed to or have contracted the flu.

Specifically regarding your information about foreign sources of flu vaccine, we have been working with foreign suppliers of flu vaccine to determine whether any excess supplies they have could be procured for use in the United States. This is an unprecedented step, and current law permits their safe and effective use only after appropriate controls and safeguards have been established to protect Americans who choose to take these products. The FDA is hopeful that significant additional doses will be identified and procured for this flu season in a manner that assures the safety and effectiveness of the product as well as the integrity of the system through which it would be delivered and subsequently administered.

In your letter, you indicated that utilizing your own contacts you were able to identify through foreign distributors some additional foreign-version flu vaccine that is not licensed for use in this country. We understand you are working with one or possibly several "middlemen." Any potentially safe and effective supply is of great interest, thus we want to work with you and would be pleased to further assess the quality of the products you have identified, and explore what might be required to make it available in the United States.

In the circumstances you have described where vaccine is already in the distribution chain, it would be important for us to collect additional information about the quality of these vaccines. Specifically, it will be important to understand the source(s) of these supplies if they are not being made available directly from the manufacturer; the standards to which these unlicensed vaccines conform; the current integrity of these products (e.g., where they are located, how they are being stored and maintained, and how they would be shipped); as well as the parties who would be responsible for their delivery to the United States.

We stand ready to work diligently with the State of Illinois in evaluating the products you speak of so that, if they can be safely distributed, it can be done so as soon as practicable.

Finally, as we work on your request, it would be help us expedite matters if we can ascertain from you what responsibilities the State of Illinois plans to assume to enable distribution and use of these products in your state. For example, how do you plan to monitor safety controls for administration of the vaccine, provide informed consent to patients receiving these vaccines, assure adequate labeling of these foreign products and provide liability protection for your consumers for the products you wish to provide them? Your answers to these questions will help expedite resolving important safety questions regarding distribution of the vaccine you have obtained from foreign sources. I am sure you agree that we need to make sure that every shot that goes into the arms of Illinois citizens and Americans is safe and effective; afterall, this is why we did not allow the distribution of the Chiron vaccine.

I have instructed my staff to contact your health department officials to further respond to your questions. Please let me know if I can be of further assistance.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D
Acting Commissioner
Food and Drug Administration